

REMARKS

Before entry of this Amendment, claims 1-25 were pending in the application. After entry of this Amendment claims 1 – 9 and 12 – 25 remain pending under examination. The number of total claims has not been increased, and the number of independent claims has not been increased beyond the number for which payment previously had been made.

Applicants have carefully considered the Examiner's Action of July 17, 2009, and the references cited therein. The following is a brief summary of the Action. Claims 1-6 and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al (USP 4,850,953). Claims 7 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al (USP 4,850,953). Claims 8-14, 16-18 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis (USP 5,667,479). Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis, and in further view of Mulhauser et al (USPUB 2003/0181879). Claims 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis and further in view of Salama (USP 6,527,755). Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis and further in view of Kim (USP 5,569,216).

For the reasons explained below, applicants respectfully traverse the rejection of claims 1-6 and 21 under 35 U.S.C. 102(b) as being anticipated by Haber et al.

The present invention pertains to a closing system for a natural or artificial anus. Haber et al discloses a valve through which liquid nourishment can be delivered through

the abdominal wall 50 and abdominal mucosa 52 of a baby that otherwise is unable to eat normally via the mouth and esophagus.

Claim 1 has been amended in accordance with the limitations formerly expressed in claims 10 and 11, and claims 10 and 11 have been cancelled. Thus, claim 1 requires:

a first cylindrical sleeve defining a first lumen with a first diameter and a second cylindrical sleeve defining a second lumen with a second diameter, said second sleeve having a portion nesting within the first lumen of said first sleeve, * * * said first end [of the hose segment] is connected to said first sleeve and forms a continuous pathway with said first lumen and said second end [of the hose segment] is connected to said second sleeve and forms a continuous pathway with said second lumen.

Applicant therefore respectfully submits that claims 1-6 and 21 are patentable under 35 U.S.C. 102(b) over Haber et al.

Claim 21 also has been amended in accordance with the last two sentences of paragraph 0007 of applicant's application publication no. 2007/0021651 to require the portion of the inner wall of the inflated balloon disposed internally of the wearer defining an internal area configured without any rigid guide shaft therein that otherwise might project into the wearer's intestine. Thus, claim 21 precludes any rigid guide shaft in an internal area defined by the inner portion of the inflated balloon, which is the central lumen of the torus geometry.

Reference to Haber et al Figs. 2, 3 and 4 for example shows that Haber et al fails to satisfy this requirement of the flexible tube segment being **configured without any rigid guide shaft**. For the Haber et al feeding lumen 6 with its tapered distal nose 7 constitutes just such a **rigid guide shaft** that claim 1 precludes.

This claim 1 feature is explained at paragraph 0007 of applicant's application publication no. 2007/0021651 as follows:

It is of **great importance that the balloon has no guide shaft**, so no such element, even one of reduced diameter, projects into the intestine. In the absence of a guide shaft, in the invention **the inner wall of the torus is formed by the balloon itself**; hence its high flexibility.

This condition cannot be achieved by the Haber et al device. For in the Haber et al device, the inner wall of the torus is formed by the rigid stem 6 in the middle.

Accordingly, applicant therefore respectfully submits that claim 21 is patentable under 35 U.S.C. 102(b) over Haber et al for this additional reason.

For the reasons explained below, applicant respectfully traverses the rejection of claims 1, 8, 9, 12-14, 16-18, 21 and 23 under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis.

Lines 2 – 7 of paragraph 12 on page 5 of the July 2009 Office Action contend that:

Kieturakis discloses said plug comprises two sleeves (figure 3, items 10 and 20) that can be fitted one inside the other and in that a mouth of each connection port (figure 3, items 62 and 66) is connected to a respective one of said sleeves; wherein the mouth that is connected to an outer of the sleeves has a diameter adapted to the outer sleeve, and the mouth that is connected to the inner of the two sleeves has a diameter adapted to the inner sleeve (figure 3).

However applicant respectfully submits that this contention is not enough to render claim 1 unpatentable, because despite this disclosure, Kieturakis fails to correct the deficiencies noted above in Haber et al.

Kieturakis discloses a resection instrument 5 that is suitable for mobilizing the esophagus in a transhiatal esophagectomy. Kieturakis FIG. 1 shows plastic handle 7 coupled to an outer guide tube 10, which has proximal and distal ends respectively 11 and 12 and is made from a thin-wall metal, plastic or glass fiber with a bore 15 extending therethrough along an axis 16. The handle 7 also is coupled to an instrument guide tube 20 that has a proximal end 21 and a distal end 22 and is a thin-wall tube made of metal, plastic or glass fiber with a bore 25 extending therethrough along axis 16. Thus, each of Kieturakis outer guide tube 10 and instrument guide tube 20 is rigid.

As shown in Kieturakis FIGS. 4 – 5, an enveloping sleeve member 40 is formed into an outer sleeve 42 and a lumen sleeve 44 extending around axis 16. As shown in Kieturakis FIG. 3, the space between outer sleeve 42 and lumen sleeve 44 is an inflation chamber 60. The proximal end 62 of outer sleeve 42 is sealed to the distal end 12 of guide tube 10 with adhesives and metal sealing ring 63. Similarly, the proximal end 66 of lumen sleeve 44 is sealed to the distal end 22 of instrument tube 20 with adhesives and metal sealing ring 68.

However, as explained at Kieturakis column 4, lines 31 – 33, only lumen sleeve 44 may be made from elastomeric material such as latex. The Kieturakis outer sleeve 42 does not stretch with increasing pressure in chamber 60. Moreover, as shown in Kieturakis FIGS. 8 – 11 and explained at column 5, lines 32 – 40 (emphasis added):

as chamber 60 is inflated, the non-elastomeric plastic sheet material of **outer sleeve 42 expands to its maximum**

diameter and thereafter inflation **pressure is directed radially inward on lumen sleeve 44 toward axis 16**. As described above, the lumen sleeve 44 only may be fabricated of elastomeric material (e.g., latex or silicon) and such material may have a gripping surface (not shown) such as a sticky, textured or ribbed surface **to better grip an anatomic structure captured within lumen 50**.

Thus, in the Kieturakis device, the outer sleeve 42 restricts expansion outwardly and directs **expansion of the lumen sleeve 44 maximally inwardly** to collapse on the central axis 16 as shown in Kieturakis FIGS. 8 – 11. However, this Kieturakis configuration is directly contrary to the requirement of the structure in Haber et al, which **prevents expansion inwardly** due to the presence of the hollow feeding stem 6 that causes **expansion of the membrane 8 only outwardly**. It is well settled that a combination or modification of references that directly contradicts the intended purpose of the primary reference (in this case Haber et al) is improper. M.P.E.P. § 2143.01 states:

If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

Under these circumstances, any proposed selection from the entirety of what is taught in Kieturakis must be regarded as having been guided by applicant's disclosure and therefore impermissible hindsight. Therefore, applicant respectfully submits that the assertion that the person of ordinary skill would modify Haber et al as taught in Kieturakis to configure the sleeves in relation to the ends of the inverted hose segment as required by applicant's claim 1, cannot be sustained.

Accordingly, in view of the deficiencies noted above in Haber et al, which deficiencies cannot be cured by Kieturakis, applicant respectfully submits that claims 1,

8, 9, 12-14, 16-18, 21 and 23 are patentable under 35 U.S.C. 103(a) over Haber et al in view of Kieturakis.

For the reasons explained below, applicant respectfully traverses the rejection of claims 7 and 22 under 35 U.S.C. 103(a) as unpatentable over Haber et al.

In view of the deficiencies noted above in Haber et al and Kieturakis, applicant therefore respectfully submits that claims 7 and 22, as presented herein, are patentable under 35 U.S.C. 103(a) over Haber et al.

For the reasons explained below, applicants respectfully traverse the rejection of claim 15 under 35 U.S.C. 103(a) as unpatentable over Haber et al in view of Kieturakis, and in further view of Mulhauser et al.

Mulhauser et al fails to correct the deficiencies noted above in Haber et al and Kieturakis. Accordingly, applicant therefore respectfully submits that claim 15 is patentable under 35 U.S.C. 103(a) over Haber et al in view of Kieturakis, and in further view of Mulhauser et al.

For the reasons explained below, applicants respectfully traverse the rejection of claims 19 and 20 under 35 U.S.C. 103(a) as unpatentable over Haber et al in view of Kieturakis and further in view of Salama.

Salama fails to correct the deficiencies noted above in Haber et al and Kieturakis. Accordingly, applicant therefore respectfully submits that claims 19 and 20 are patentable under 35 U.S.C. 103(a) over Haber et al in view of Kieturakis and further in view of Salama.

For the reasons explained below, applicants respectfully traverse the rejection of claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Haber et al in view of Kieturakis and further in view of Kim.

Kim fails to correct the deficiencies noted above in Haber et al and Kieturakis. Accordingly, applicant therefore respectfully submits claims 24 and 25 are patentable under 35 U.S.C. 103(a) over Haber et al in view of Kieturakis and further in view of Kim.

Applicant respectfully requests reconsideration and reexamination of claims 1 – 9 and 12 – 25, as presented herein, and submits that these claims are in condition for allowance and should be passed to issue.

If any fee or extension of time is required to obtain entry of this Amendment, the undersigned hereby petitions the Commissioner to grant any necessary time extension and authorizes charging Deposit Account No. 04-1403 for any such fee not submitted herewith.

Respectfully submitted,

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DATE: Oct 16, 2009

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